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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,648	03/07/2001	Neil A. Williams	7438	3732

26850 7590 04/12/2002
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EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,648

Applicant(s)

WILLIAMS ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 29-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Election/Restrictions

- | | |
|-----------|--|
| Group I | Claims 29-33 are drawn to a method of treating a subject having a disease associated with an immune disorder comprising administering the subject an effective amount of a peptide wherein the peptide does not exhibit GM-1 binding activity. |
| Group II | Claims 34-38 are drawn to a method of treating a subject having an autoimmune disease, human T cell leukemia, transplant rejection or graft-verses –host disease, allergies or infectious disease comprising administering to the subject an effective amount of a peptide wherein the peptide does not exhibit GM-1 binding activity. |
| Group III | Claims 39-44 are drawn to a method of treating a subject having diarrhea comprising administering to the subject an effective amount of a peptide wherein the peptide does not exhibit GM-1 binding activity. |
| Group IV | Claims 45-49 are drawn to a method of treating a subject having a toxin-mediated disorder comprising administering to the subject an effective amount of a peptide wherein the peptide does not exhibit GM-1 binding activity. |

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2. In the event applicant elects Group I, claims 29-33 applicant is required to elect a single SEQ ID No. Claims 29-33 recite two distinct SEQ ID Nos., based on structural differences, comprising:

Species A, drawn to SEQ ID NO: 2.

Species B, drawn to a sequence that exhibits 75% homology to SEQ ID NO:2

Species C, drawn to SEQ ID NO: 3.

Species D, drawn to a sequence that exhibits 75% homology to SEQ ID NO:3

Species E, drawn to SEQ ID NO: 4

Species F, drawn to a sequence that exhibits 75% homology to SEQ ID NO:4

Species G, drawn to SEQ ID NO: 5.

Species H, drawn to a sequence that exhibits 75% homology to SEQ ID NO:5

3. In the event applicant elects Group II, claims 34-38 applicant is required to elect a single SEQ ID No. Claims 29-33 recite two distinct SEQ ID Nos., based on structural differences, comprising:

Species A, drawn to SEQ ID NO: 2.

Species B, drawn to a sequence that exhibits 75% homology to SEQ ID NO:2

Species C, drawn to SEQ ID NO: 3.

Species D, drawn to a sequence that exhibits 75% homology to SEQ ID NO:3

Species E, drawn to SEQ ID NO: 4

Species F, drawn to a sequence that exhibits 75% homology to SEQ ID NO:4

Species G, drawn to SEQ ID NO: 5.

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Species H, drawn to a sequence that exhibits 75% homology to SEQ ID NO:5

4. In the event applicant elects Group III, claims 39-44 applicant is required to elect a single SEQ ID No. Claims 29-33 recite two distinct SEQ ID Nos., based on structural differences, comprising:

Species A, drawn to SEQ ID NO: 2.

Species B, drawn to a sequence that exhibits 75% homology to SEQ ID NO:2

Species C, drawn to SEQ ID NO: 3.

Species D, drawn to a sequence that exhibits 75% homology to SEQ ID NO:3

Species E, drawn to SEQ ID NO: 4

Species F, drawn to a sequence that exhibits 75% homology to SEQ ID NO:4

Species G, drawn to SEQ ID NO: 5.

Species H, drawn to a sequence that exhibits 75% homology to SEQ ID NO:5

5. In the event applicant elects Group IV, claims 45-49 applicant is required to elect a single SEQ ID No. Claims 29-33 recite two distinct SEQ ID Nos., based on structural differences, comprising:

Species A, drawn to SEQ ID NO: 2.

Species B, drawn to a sequence that exhibits 75% homology to SEQ ID NO:2

Species C, drawn to SEQ ID NO: 3.

Species D, drawn to a sequence that exhibits 75% homology to SEQ ID NO:3

Species E, drawn to SEQ ID NO: 4

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Species F, drawn to a sequence that exhibits 75% homology to SEQ ID NO:4

Species G, drawn to SEQ ID NO: 5.

Species H, drawn to a sequence that exhibits 75% homology to SEQ ID NO:5

6. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I and Group II lacks novelty under PCT Article 33(2) as being anticipated by Williams et al (*U.S. Patent No. 6, 287, 563, filed December 29, 1997*).

Williams et al discloses agents in the treatment or prevention of human cell leukemia, transplant rejection or graft-verses –host disease in a vaccination method for vaccinating a mammalian subject. Williams et al also disclose that the agents used in vaccinating a mammalian subject can be an agent having an effect on GM-1 binding mediated intracellular signaling events but no GM-1 binding activity (see the Abstract). Groups I and II lack novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

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7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford
Biotechnology Patent Examiner
April 8, 2002



LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER